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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,140	11/21/2000	Brian Hawtin	2000-0702.OR	6011

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EXAMINER	
WELLS, LAUREN Q	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/701,140	HAWTIN, BRIAN	
	Examiner	Art Unit	
	Lauren Q Wells	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,9,11-13,15,17,21-23,28 and 31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *13* is/are allowed.

6)☒ Claim(s) *1,3-5,9,11,12,15,17,21-23,28 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 3-5, 9, 11-13, 15, 17, 21-23, 28, 31 are pending. The Amendment filed 9/29/2003, amended claim 1.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/3/2003 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-5, 9, 11-12, 17, 23, 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The addition of the phrase "said composition being adapted to provide transdermal transmission of said polar drug" is new and lacks support in the original disclosure. Nowhere in the original disclosure is there support for the inventive composition providing transdermal transmission to the polar drug.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 4, 5, 11, 17, 23, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Totten et al. (GB 2202145) in view of Jacobs et al. (5,939,085) and Sang et al. (6,143,310).

The instant invention is directed toward a composition comprising an amphoteric surfactant, a polypropoxylated cetyl alcohol, a polar selected from sodium cromoglycate and nedocromil sodium, and an aqueous and oil phase.

Totten et al. teach compositions of nedocromil for dermatological use. Oil-in-water emulsions are preferred forms of the compositions. The oil phase can comprise surfactants, such as cetomacrogol ethers, wherein cetomacrogol ether is an ethoxylated cetyl alcohol. Topical administration of the composition is disclosed. The composition is filled into 20ml tubes. The reference lacks polypropoxylated cetyl alcohol and an amphoteric surfactant. See pg. 2, line 18-pg. 3, line 7; pg. 4, line 1-pg. 5, line 5; pg. 6, lines 19-22; pg. 7, lines 5-23; pg. 9-pg. 12.

Jacobs et al. teach skin smoothing compositions. Oil-in-water emulsions are taught, wherein disodium cocoamphodiacetate is a preferred surfactant. Disodium cocoamphodiacetate functions as an oil-in-water emulsion stabilizer and as a skin smoothing agent. See Col. 4.

Sang et al. teach cosmetic compositions. PPG-5-Ceteth is taught as a preferred alkoxylated cetyl alcohol that acts as a surfactant and solubilizes negatively charged active agents. See Col. 10.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the disodium cocoamphodiacetate of Jacobs et al. to the oil-in-water emulsions of Totten et al. because of the expectation of stabilizing the oil-in-water emulsions and smoothing the skin.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the PPG-5-ceteth of Sang in substitution for the cetomacrogol ether of Totten et al. because a) Sang et al. and Totten et al. are both directed toward skin cosmetic compositions; b) Totten et al. teach that additional surfactants can be added to his composition, especially alkoxylated surfactants; c) Sang et al. teach PPG-5-ceteth as both polyethoxylated and polypropoxylated, wherein these compounds are useful as surfactants for stabilizing emulsions and negatively charged active agents; thus, one of skill in the art would be motivated to substitute one for the other because of the expectation of achieving similar surfactant properties and as providing stability to the negatively charged active agent.

The claims are directed to a composition comprising an amphoteric surfactant, a polypropoxylated cetyl alcohol, and sodium cromoglycate or nedocromil sodium. Any properties exhibited by or benefits provided the composition are inherent and are not given patentable weight over the prior art. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties Applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655,

1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not inherently possess the same properties as instantly claimed product. The combined prior art teaches compositions containing the same components as instantly claimed, which would inherently provide transdermal transmission of the polar drug as instantly claimed. Applicant has not provided any evidence of record to show that the prior art compositions do not exhibit the same properties as instantly claimed.

Regarding claim 23, it is respectfully pointed out that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In the instant case, the intended use of the composition is not afforded patentable weight.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Totten et al. in view of Jacobson et al. and Sang et al. as applied to claims 1, 3, 4, 5, 11, 17, 23, and 28 above, and further in view of Dener et al. (WO 98/04537) and Haider (1979).

Totten et al., Jacobson et al., and Sang et al. are applied as discussed above. The references lack corticosteroids.

Dener et al. teach compositions for treating hyperproliferative skin diseases and inflammatory skin conditions. Cromolyn and nedocromil are taught as equivalent cromoglycates. See abstract.

Haider teaches the treatment of atopic eczema with sodium cromoglycate. Compositions comprising sodium cromoglycate and hydrocortisone are disclosed to treat patients with severe inflammation. See pages 572-573.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the hydrocortisone of Haider to the composition of the combined references because a) Dener et al. teach cromolyn and nedocromil as equivalent cromoglycates for use in skin conditions, and Totten et al. teach nedocomil for the treatment of skin conditions; b) Haider teaches the combination of sodium cromoglycate (cromolyn) and hydrocortisone as treating significant inflammation in patient's with eczema (an inflammatory skin condition); thus, one of skill in the art would be motivated to add hydrocortisone to the composition of the combined references because of the expectation of synergistically decreasing the inflammation of skin conditions.

Claim 12 rejected under 35 U.S.C. 103(a) as being unpatentable over Totten et al. in view of Jacobson et al. and Sang et al. as applied to claims 1, 3, 4, 5, 11, 17, 23, and 28 above, and further in view of the Handbook of Cosmetic Science and Technology.

Totten et al., Jacobson et al., and Sang et al. are applied as discussed above. The references lack foams.

The Handbook of Cosmetic Science and Technology teaches emulsions and foams as interchangeable colloid systems. See page 67.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the emulsions of the combined references in the form of foams, as taught by the Handbook of Cosmetic Science and Technology, because of the expectation of achieving

equivalent colloidal systems and because of the expectation of achieving a product that can be more evenly and easily applied to a specific area of a user.

Claims 15 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Totten et al. in view of Jacobs et al.

Totten et al. teach compositions of nedocromil for dermatological use. Oil-in-water emulsions are preferred forms of the compositions. The oil phase can comprise surfactants, such as cetomacrogol ethers, wherein cetomacrogol ether is an ethoxylated cetyl alcohol. Topical administration of the composition is disclosed. The compositions are specifically taught for treating systemic sclerosis, morphoea, and dermal nodular fibrosis. The reference lacks an amphoteric surfactant. See pg. 2, line 18-pg. 3, line 7; pg. 4, line 1-pg. 5, line 5; pg. 6, lines 19-22; pg. 7, lines 5-23; pg. 9-pg. 12.

Jacobs et al. teach skin smoothing compositions. Oil-in-water emulsions are taught, wherein disodium cocoamphodiacetate is a preferred surfactant. Disodium cocoamphodiacetate functions as an oil-in-water emulsion stabilizer and as a skin smoothing agent. See Col. 4.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the disodium cocoamphodiacetate of Jacobs et al. to the composition of Totten et al. because of the expectation of stabilizing the oil-in-water emulsion and smoothing the skin.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Totten et al. in view of Jacobs et al. as applied to claims 15 and 21 above, and further in view of Sang et al.

Totten et al. and Jacobs et al. are applied as discussed above. The reference lacks polypropoxylated cetyl alcohol.

Sang et al. teach cosmetic compositions. PPG-5-Ceteth is taught as a preferred alkoxylated cetyl alcohol that acts as a surfactant and solubilizes negatively charged active agents. See Col. 10.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the PPG-5-ceteth of Sang in substitution for the cetomacrogol ether of the combined references because a) Sang et al. and the combined references are both directed toward skin cosmetic compositions; b) the combined references teach that additional surfactants can be added to his composition, especially alkoxylated surfactants; c) Sang et al. teach PPG-5-ceteth as both polyethoxylated and polypropoxylated, wherein these compounds are useful as surfactants for stabilizing emulsions and negatively charged active agents; thus, one of skill in the art would be motivated to substitute one for the other because of the expectation of achieving similar surfactant properties and as providing stability to the negatively charged active agent.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Totten et al. in view of Jacobson et al. as applied to claims 15 and 21 above, and further in view of Dener et al. and Haider.

Totten et al. and Jacobson et al. are applied as discussed above. The reference lacks corticosteroids.

Dener et al. teach compositions for treating hyperproliferative skin diseases and inflammatory skin conditions. Cromolyn and nedocromil are taught as equivalent cromoglycates. See abstract.

Haider teaches the treatment of atopic eczema with sodium cromoglycate. Compositions comprising sodium cromoglycate and hydrocortisone are disclosed to treat patients with severe inflammation. See pages 572-573.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the hydrocortisone of Haider to the composition of the combined references because a) Dener et al. teach cromolyn and nedocromil as equivalent cromoglycates for use in skin conditions, and Totten et al. teach nedocomil for the treatment of skin conditions; b) Haider teaches the combination of sodium cromoglycate (cromolyn) and hydrocortisone as treating significant inflammation in patient's with eczema (an inflammatory skin condition); thus, one of skill in the art would be motivated to add hydrocortisone to the composition of the combined references because of the expectation of synergistically decreasing the inflammation of skin conditions.

Allowable Subject Matter

The composition recited in instant independent claim 13 is neither anticipated nor rendered obvious over the prior art. The closest prior art is GB 2202145, which teaches a composition comprising 4% glyceryl monostearate, 10% liquid paraffin, 5% isopropyl myristate, 67.22% water, and 4% of a polar drug, and other ingredients. However this composition lacks disodium edetate, amphoteric surfactant, alkoxylated cetyl alcohol, triclosan, sorbitan tristearate or non-ionic emulsifying wax, and benzyl alcohol, and this composition additionally contains Cremophor A6, Cremophor A25, propyl hydroxybenzoate, methyl hydroxybenzoate, potassium sorbate, sodium acid citrate, and sodium hydroxide.

Response to Arguments

Applicant argues that there is no motivation to add the surfactant of Jacobs et al. to the composition of Totten et al., "the surfactant characteristics described in Jacobs et al. '085 are not wont for lacking in Totten et al. '145, nor would such characteristics lead to the unexpected results of the present invention". This argument is not persuasive. The Examiner respectfully points out that the teachings of both Totten et al. and Jacobs et al. are directed toward oil-in-water emulsions for application to the skin. Jacobs et al. teach disodium cocoamphodiacetate as having superb emulsification, and hence stability, effects on the emulsions. Thus, there is motivation to combine the references. Regarding the argument of unexpected results, it is respectfully pointed out that Applicant has not provided persuasive evidence of unexpected results.

Applicant argues, "the cited references fail to provide an incentive to combine respective components into the presently claimed compositions. Namely, Jacobs et al. '085 describe a surfactant in an emulsion, but does not suggest combining such a surfactant with an alkoxylated cetyl alcohol. Similarly, Sang et al. '310 describes an alkoxylated cetyl alcohol in an emulsion, but does not suggest combining such an alkoxylated cetyl alcohol with an amphoteric surfactant". This argument is not persuasive. It is respectfully pointed out that Jacobs et al. and Sang et al. both teach surfactants that increase the stability of emulsions, and that it is well established in the emulsion art to combine surfactants to increase the stability of emulsions. Additionally, regarding Sang et al., it is respectfully pointed out that Totten et al. teach their emulsions as comprising alkoxylated surfactants and that Sang et al. is merely relied upon to teach a preferred alkoxylated surfactant.

Regarding Applicant's argument that the Examiner has inappropriately picked and chosen from different references, this argument is not persuasive. See the above paragraphs and rejections, wherein the motivation to combine the references is clearly stated.

Applicant argues, regarding the Alan Edwards affidavit, "Exhibits A and B which represent statistical and practical comparisons between Totten et al. '145 and the presently claimed compositions. In short, the enclosed Declaration with Exhibits A and B demonstrate that the claimed compositions are clinically effective while those of Totten et al. '145 fail". This argument is not persuasive. First, the Examiner respectfully points out that there is no comparative data between the compositions of the instant invention and that of Totten et al. Second, it is respectfully pointed out that there is no evidence that the compositions of Van Bever et al. and those of Totten are the same. Third, the tables of Exhibit A fail to provide results of statistical significance, and it is not clear if the compositions relied upon in these tables are even commensurate in scope with the instant claims.

It is respectfully pointed out that Applicant continues to argue that he has achieved unexpected results based on the method of use of the composition. It is respectfully pointed out that such arguments are not commensurate in scope with the instant claims, the majority of which are directed to compositions and not to methods. It is respectfully pointed out that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA

1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In the instant case, the method of use of the composition claims is not afforded patentable weight.

Applicant argues that he has satisfied a long-felt need. This argument, however, is not persuasive, as the Applicant has provided no evidence a) establishing a long-felt need and; b) alleviating a long-felt need by the instant invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is 571-272-0634. The examiner can normally be reached on M&R (5:30-4).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

lqw

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